following variables were identified as predictors of poor image quality in descending order of frequency: BSL valve (Odds 3.5 IC 95% [1.3 - 9.6], p=0.02), presence of an artifact (Odds 2.5 IC 95% [1.2 - 5.4], p=0.02) and BMI (Odds 1.1 IC 95% [1.0 - 1.2], p=0.04).

CONCLUSIONS R-angio with dedicated motion compensation software offers good image quality for on-line frame analysis in 72% of the patients. Image quality predominantly depends on valve type, presence of artefacts and patient-related variables such as BMI. "Disclaimer: The concepts and information presented in this paper are based on research and are not commercially available."

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Rotational angiography, Transcatheter aortic valve replacement

TCT-613

Extracranial Carotid And Vertebral Artery Disease And The Risk Of Stroke Following Trans-catheter Aortic Valve Replacement

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BACKGROUND Stroke is a feared complication of trans-catheter aortic valve replacement (TAVR). Carotid and vertebral artery duplex ultrasonography is routinely obtained prior to TAVR, but the significance of extracranial carotid and vertebral artery disease (CVD) on the risk of stroke following TAVR is unknown. The purpose of this study is to assess the impact of CVD on the risk of stroke following TAVR.

METHODS We reviewed 294 consecutive cases of TAVR at a single tertiary care academic medical center from June, 2008 to March, 2015. We included 263 patients who underwent routine carotid and vertebral artery duplex ultrasonography prior to TAVR in a retrospective cohort study. Patients with at least 50% stenosis of a carotid or vertebral artery were identified as having CVD, and patients were stratified into 2 groups by the presence or absence of CVD. The primary outcome was stroke within 30 days of TAVR. We adjudicated stroke by the guideline recommendations of the Valve Academic Research Consortium. Secondary outcomes included 30-day mortality and overall survival following TAVR. We used chi2 and Fischer's exact tests to compare categorical variables and independent samples t tests to compare continuous variables. We used Kaplan Meier life table analysis to assess overall survival. We included univariate predictors of stroke at P<0.10 in a multivariable logistic regression to identify predictors of stroke after TAVR.

RESULTS CVD was present in 51 (19%) patients. The CVD group had higher rates of coronary artery disease, prior coronary artery bypass surgery, and peripheral artery disease compared to the non-CVD group. There was no significant difference in the rate of prior stroke or the burden of aortic atheroma by intra-operative trans-esophageal echocardiogram between CVD and non-CVD patients. Trans-femoral access was less common in the CVD group (55% vs. 77%, p<0.01). Stroke occurred in 18 (6.8%) patients within 30 days after TAVR. No patients with CVD suffered a stroke. There was no difference in 30-day mortality (10% vs 4%, p=0.11) and overall survival (log-rank test, p=0.89) between the CVD and non-CVD groups. CVD was not a significant predictor of stroke following TAVR by logistic regression. In a multivariable model, there were no significant independent predictors of stroke after TAVR, but baseline antiplatelet therapy showed a trend towards a protective effect, and higher pre-TAVR mean aortic valve gradient showed a trend toward increased risk of stroke (table).

Predictors of Stroke Following TAVR	Odds Ratio	95% Confidence Interval	P
Prior coronary artery bypass surgery	0.33	0.04 to 1.89	0.32
Prior dyslipidemia	0.40	0.11 to 1.38	0.15
Baseline antiplatelet therapy	0.29	0.08 to 1.02	0.05
Aortic atherosclerosis > 2mm thickness	3.71	0.68 to 20.12	0.13
Trans-aortic access	3.41	0.56 to 20.97	0.19
Pre-TAVR mean aortic valve gradient (increasing continuous variable by mm Hg)	1.05	1.00 to 1.11	0.07

CONCLUSIONS CVD is not associated with an increased risk of stroke or death following TAVR. The routine screening of CVD prior to TAVR does not appear justified.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Carotid stenosis, Stroke, Transcatheter aortic valve replacement

TCT-614

Aortic Root and Annular Anatomical Exclusion for Transcatheter Aortic Valve Implantation

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BACKGROUND Patients with severe aortic stenosis who are referred for transcatheter aortic valve replacement (TAVR) need to meet aortic root and aortic annular anatomical inclusion criteria. We sought to characterize the number of patients that could not have the currently available transcatheter valves (Sapien XT and CoreValve).

METHODS We screened 400 patients with severe aortic stenosis who were referred for TAVR between 2010-2014 who had had multi-detector computed tomographic (MDCT) imaging. Annulus measurements of the basal ring (short- and long-axis, area-derived diameter), coronary ostia height, sinus area (SA), sino-tubular junction area (STJ), calcification and eccentricity index (EI, 1-short axis/long axis) were made.

RESULTS The vast majority of patients were able to be offered a currently available TAVR valve (88%). We identified 49 patients who were excluded for anatomical annular characteristics alone. Large aortic annuli were the most common reason for anatomical exclusion [704 ± 79 mm2; (n= 39, 80 %)]. In addition these large annuli were more elliptical (EI, 1.39 ± 0.1) with more eccentric calcification (68 %). The presence of low coronary heights (n=6 mm: n=19, 18 %) from the aortic annular plane was the next most common reason. The left main coronary artery was more commonly lower than the right coronary artery and low coronary heights with effaced coronary sinuses appeared occur together (n=11, 57 %). Small aortic annuli were the least common [290 ± 50 mm2; n=1, 2 %) cause for exclusion from TAVR therapy. None of the patients who were excluded form TAVR therapy had more than one annular reason for TAVR exclusion.

CONCLUSIONS Most patients with severe aortic stenosis who are referred for TAVR can be offered a transcatheter valve. However, 12 % of patients cannot be offered a therapy due to annular anatomical exclusion criteria. This was primarily due to the presence of large aortic annuli and low coronary heights.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, TAVR

TCT-615

First Report of Three-Year Outcomes With the Repositionable and Fully Retrievable Lotus Aortic Valve Replacement System: Results From the REPRISE I Feasibility Study

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BACKGROUND The repositionable, fully retrievable, CE-marked Lotus Valve is designed to facilitate controlled, precise positioning and minimize paravalvular aortic regurgitation. Results to 3 years post-implantation with Lotus have not yet been reported.

METHODS REPRISE I is a prospective, single-arm, 3-center feasibility study designed to assess acute safety and performance of the 23mm Lotus Valve in symptomatic patients with calcified aortic stenosis who were considered high surgical risk by the Heart Team.

RESULTS The Lotus Valve was implanted in 11 female patients with a mean age 83.0±3.6 years and a mean STS score 4.9±2.5%). Frailty measures included gait speed ≥6s (9/11), grip strength ≤18kg (7/11), and cognitive dysfunction (5/11; defined as a score <4 on the

Mini-Cognitive Assessment for Dementia). All (11/11) patients were successfully implanted with a Lotus Valve with no procedural mortality. All patients remained alive at 2 years, and the 2-year clinical follow-up and TTE assessment rates were 100% (11/11). Major stroke occurred in 1 patient on day 3, for a 2-year major stroke rate of 9.1%, and life-threatening/disabling bleeding occurred in 2 patients for a 2-year rate of 18.2%. Conduction disturbance requiring new permanent pacemaker implantation remained at 4 patients. There were no repeat hospitalizations for valve-related symptoms or cardiac decompensation. Mean aortic gradient was 15.5±4.4mmHg and mean effective orifice area was 1.51±0.19cm^2 at 2 years. All (100%) patients remained in New York Heart Association Class I or II. Core laboratory adjudicated paravalvular aortic regurgitation was not evaluable in 1 patient, trace/trivial in 1 patient, mild in 1 patient, and absent in 8 patients at 2 years.

CONCLUSIONS Two-year feasibility results suggest that the Lotus Valve has minimal aortic regurgitation and low clinical event rates sustained through 2 years. Three-year outcomes from REPRISE I will be available for presentation for the first time at TCT 2015.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic valve stenosis, Clinical Trial, Transcatheter aortic valve replacement

TCT-616

Utility And Safety Of Temporary Pacing Using Active-fixation Leads And Externalized Re-Usable Permanent Pacemakers In Transcatheter Aortic Valve Implantation

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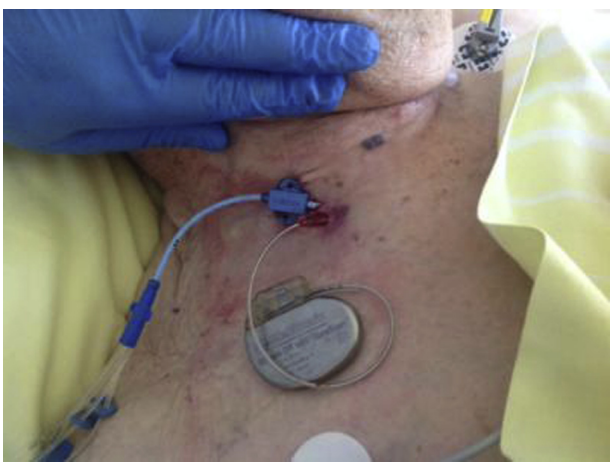
BACKGROUND With the beginning of transcatheter aortic valve implantation (TAVI), the use of active-fixation leads combined with externalized re-usable permanent pacemakers was initiated to improve lead stability, increase patient mobility and facilitate handling for nursing staff. Experience and benefits of temporary permanent pacemaker (TPPM) systems have thus far mainly been reported in patients suffering from cardiovascular implantable electronic device (CIED) infection. The aim was to investigate the safety and efficacy of TPPMs for periprocedural rapid ventricular pacing and postprocedural back-up pacing in patients undergoing transcatheter aortic valve implantation (TAVI).

METHODS Between November 2008 and April 2015, a temporary permanent pacemaker system was implanted in 108 consecutive TAVI patients. An active-fixation right-ventricular lead was implanted in either an apical or septal position via the right internal jugular vein using a 7 French peel-away introducer sheet. Pacing treshold was considered acceptable if <1.0 V at a pulse width of 0.5 ms, as were R-wave sensing amplitudes > 10 mV. The lead was then sutured to the patient's neck and connected to a re-usable permanent pacemaker programmed in VVI mode. Finally, the pacemaker and lead were taped to the patient's skin in typical infraclavicular position.



RESULTS Mean patients' age was 81.1 ± 4.9 years and mean duration of TPPM was 5.6 ± 2.1 (range 2-14) days. After successful primary implantation in all patients without any procedure-related complications defined as pneumothorax, pericardial effusion with hemodynamic relevance and local infection or hematoma, lead dislocation and necessity of lead repositioning occurred in one patient (0.92%).

Patients	108
Male (female)	44 (64)
Age (years)	81.1 ± 4.9
Success of temporary lead implantation, n (%)	108 (100)
Apical positioning, n (%)	68 (63)
Septal positioning, n (%)	40 (37)
No. of days TPPM (range)	5.6 ± 2.1 (2-14)
Procedure-related complications	0
Lead dislocation, n (%)	1 (0.92)

CONCLUSIONS Temporary permanent pacemakers using active-fixation leads are safe and effective in TAVI procedure, providing a stable pacing mechanism with a low rate of lead dislocation.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Pace maker implantation, TAVI

TCT-617

Role of aortic root phenotype in the rate of more-than-mild aortic regurgitation after Corevalve and Edwards-SAPIEN implantation

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BACKGROUND Different studies have compared the rate of more-than-mild aortic regurgitation (AR) between Corevalve (MCS) and Edwards-SAPIEN valve (ESV) with different results. Aortic root calcification has been also related with AR. For the time being, no study reported the rate of significant AR between these 2 devices in relation with the aortic root anatomy.

METHODS All consecutive patients (p) who underwent transcatheter aortic valve replacement (TAVR) with a MCS or ESV (ESV-XT or ESV-Sapien 3) and a good image quality CT-scan were included. Aortic root calcium was assessed by using the modified Agatston score, from left main to the nadir of the aortic annulus leaflets. Paravalvular AR was assessed by aortography at least 10 minutes post TAVR. Based on annulus eccentricity and Agatston score 4 phenotypes (Ph) were identified: - Ph 1: Mildly calcified aortic root and circular annulus. - Ph 2: Mildly calcified aortic root and elliptical annulus. - Ph 3: Severely calcified aortic root and circular annulus. - Ph 4: Severely calcified aortic root and elliptical annulus.

RESULTS A total of 248 p were included in the analysis (MCS=196; ESV 52). The distribution of phenotypes was as follows: for ES, ph 1 was present in 13 p (25.0 %), ph 2 in 13 p (25.0%), ph 3 in 14 p (26.9 %) and ph 4 in 12 p (23.1%). For MCS ph 1 was present in 59 p (30.1 %), ph 2 in 46 (23.5 %), ph 3 in 49 p (25.0%) and ph 4 in 42 p (21.4 %). Seventy-one p (28.6 %) patients had more than mild paravalvular AR, 7.7 % of patients with ES (4 p.) and 28.6 % (67 p) with MCS. Overall, Agatston score (4204 ± 1990 vs. 3433 ± 3269, p=0.065) and eccentricity of the annulus (18.9 ± 8.2 vs. 15.9 ± 8.5, p=0.092) were higher in patients with more-than-mild AR. In mildly calcified aortic roots, there were not differences between both devices in the rate of significant AR (MCS 16.2 % vs. ESV 11.5%, p=0.56). In severely calcified aortic roots, more than mild AR was more frequent after TAVR with MCS (MCS 54.9% vs. ESV 4.0 %, p=< 0.0001). In the analysis per ph, there were not significant differences in the rate of AR per device for phenotype 1 and 2. In ph 3 and 4 more than mild paravalvular AR was more frequent with MCS (Figure).

CONCLUSIONS In heavily calcified roots, TAVR with ESV seems to be associated with less paravalvular AR in comparison with MCS. In mildly calcified aortic roots the rate of significant AR is similar between both devices.